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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/701,295 | 11/03/2003 | Nigel Benjamin | 13227-002003 | 5269 |
| 23713 | 7590 | 05/11/2006 | EXAMINER | |
| GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301 | | | PAK, JOHN D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/701,295 | BENJAMIN ET AL. | |
| | Examiner | Art Unit | |
| | JOHN PAK | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 February 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/21/2006 has been entered.

New claims 21-27 are now pending in this application. Before turning to examination of these new claims on the merits, a review of effective filing date is necessary because of its relevance on which prior art reference may be applied against the claims.

New claims 21-27 recite or read on the following feature:

wherein said acidifying agent and said source of nitrite ions are disposed separately in respective pharmaceutically acceptable carriers for admixture at the intended environment of use and being effective to release NO or NO₂ at the environment of use.

Applicant's specification provides that the dosage forms can include tablet, paint, varnish, wax, multi-layered devices (pages 10 & 12). However, close review of related cases for which benefit of earlier filed application is claimed shows that only cream or ointment forms can have an effective filing date of the earliest claimed dates. In WO

95/22335 (publication of PCT/GB95/00338, filed on 2/17/1995), the following disclosure is found with respect to "disposed separately" feature (page 3):

The pharmaceutical acceptable carrier or diluent may be an inert cream or ointment. In a particularly preferred form of
30 the invention the acidifying agent and the source of nitrite ions or precursor therefor are separately disposed in said cream or ointment for admixture to release nitrite ions at the environment of use.

See also claim 5 of WO 95/22335:

5. A dosage form according to any preceding claim wherein the pharmaceutically acceptable carrier is disposed in an
25 inert cream or ointment, and wherein said acidifying agent and said source of nitrite ions is separately disposed in a respective cream or ointment for admixture to release nitrate ions at the intended environment of use.

Additionally, WO 95/22335 fails to disclose ascorbyl palmitate, lactic acid, citric acid, formic acid, benzoic acid and tartaric acid, which are claimed in applicant's claims 22-24, 26 and 27. It is noted that 08/696,930 is a 371 of PCT/GB95/00338, which published as WO 95/22335, so that case provides no additional disclosure support.

Above discussion applies also to foreign priority applications with earlier filing dates than WO 95/22335. Relatedly, see the Examiner's comments regarding GB 9804469.6 in the Office action of 9/12/2005.

The Examiner therefore concludes that **at best** the earliest effective filing date for the currently claimed subject matter **may be 3/1/1999**, the filing date of PCT/GB99/00605. This is because none of the earlier filed applications disclose (i) the “disposed separately” feature with respect to all dosage forms and (ii) all the acids now claimed.

Without needing to determine at this time whether the effective filing date of the instant claims is 3/1/1999 (filing date of PCT/GB99/00605) or 6/11/1999 (filing date of parent case), further examination on the merits can continue now because the difference in those dates will not be material hereinbelow.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Seitz et al. (US 6,103,275).

Seitz et al. explicitly disclose a 1.5 wt% sodium nitrite gel and a 3.3 wt% ascorbic acid gel (column 9, lines 5-13). Two separate gels are disclosed (id.). The gels are to be combined to generate NO for topical treatments (see e.g., claim 12).

The claims are anticipated because every element of applicant's claims are expressly taught or necessarily encompassed. Applicant's feature of "in an amount sufficient to establish a pH at an environment of use below 4" is noted with respect to the acid component, but it is also noted that 1-10 wt% ascorbic acid meets that feature (see applicant's claim 27, line 2). Hence, because Seitz et al. disclose 3.3 wt% ascorbic acid in a gel, this amount is sufficient to meet applicant's claim feature. Also, because Seitz's "dosage form" contains the same exact components as applicant's "dosage form," the same properties must necessarily be present. Hence, Seitz's disclosure meets applicant's feature, "for topical treatment of a bacterial, viral or fungal infection."

For these reasons, all claims are found to be anticipated.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) In claim 25, "said metal alkali nitrite" lacks antecedent basis. If applicant intends this feature to be recited in claim 21, such an amendment is suggested.

(2) After line 2 of claim 27 where it reads "1 to 10% by weight" the text becomes confusing. It can't be determined which percentages are for what substance.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **(571)272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK
PRIMARY EXAMINER
GROUP 1600